

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application of

SOUDA et al

Atty. Ref.: 423-27

Serial No. 08/354,726

Group: 1203

Filed: 6 December 1994

Examiner: Fan

For: PYRIDINE DERIVATIVES HAVING ANTI-
ULCERATIVE ACTIVITY

* * * * *

July 15, 1997



Honorable Commissioner of Patents
and Trademarks
Washington, DC 20231

Sir:

RESPONSE

This responds to the Official Action of January 15, 1997, paper No. 13.

Petition is hereby made for a three month extension of time and our check in the appropriate amount is attached.

Claims 18 and 19 remain active in the application. These claims are directed to a single compound containing a methyl thio group and its sodium salt, respectively. The compound is useful as an intermediate compound to produce

08/08/1997 DTHOMAS 00000032 08354726
01 FC:117 pharmacologically active sulfinyl compounds and in fact it is this final compound

that is the subject of claims of U.S. 5,045,552 which issued from this series of applications. It is known as rabeprazol sodium. Rabeprazol sodium possesses useful antibiotic properties and this is the subject of the evidence of record in this application.

In the outstanding Official Action the examiner indicates that "the unexpected advantage (antibiotic use) is not disclosed in the original specification".

The prior art rejection appears to be based on the expectation of obtaining similar properties for structurally similar compounds. This rejection may be overcome by showing that the claimed compound possesses a utility that the prior art compounds do not have or that they exhibit unexpected or superior properties compared with the prior art compounds. *In re Dillon*, 919 F.2d 688, 16 USPQ.2d 1897 (Fed. Cir. 1990); *Ex parte Blattner*, 2 USPQ 2d 2047, 2048 (Bd. Pat. App & Int. 1987).

The CCPA' decision in *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) is also pertinent.

[W]e think that [the Board's rejection] rests on one fundamental error of law, namely, the failure to take into consideration the biological or pharmaceutical property of the compounds as anti-inflammatory agents on the

ground that to chemists the structure of the compounds would be so obvious as to be beyond doubt, and that a showing of such properties is to be used only to resolve doubt.

From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing.... And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter. There is no basis in law for ignoring any property in making such a comparison. An assumed similarity based on a comparison of formulae must give way to evidence that the assumption is erroneous.

The examiner cites as basis for the position *In re Davies* a 1973 decision of the Court of Customs and Patent Appeals (CCPA). Counsel submits that *Davies* is not pertinent here since the claims of the present application are drawn to intermediates which lead to compounds having unexpected properties. Accordingly, the prior art-based rejection is respectfully traversed.

Claims 18 and 19 have also attracted rejections of alleged obviousness-type double patenting over the claims of U.S. patent 5,045,552. Applicants respectfully traverse this objection on the basis of the prosecution history of that patent. I refer to the Official Action of September 21, 1998, paper No. 2, in that application, a copy of which is attached. The Official Action makes a distinction between

various groups and constituents falling within the claim as originally submitted and, in effect, finds a single core structure "held in common by all the compounds within the complex molecules of the generic formula. Counsel submits that, in effect, the examiner has distinguished between the claims of the present application and the claims of the issued patent on the basis of patentably independent and distinct inventions. This, in effect, brings into play the provisions of 35 USC §121, third sentence which reads:

"A patent issuing on an application with respect to which a requirement for restriction under this section has been made, or an application filed as a result of such a requirement, shall not be used as a reference either in the Patent & Trademark Office or the Courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application".

Counsel submits that applicants are in effect "protected" by the provisions of 35 USC 121 by virtue of the decisions and framework for examination established in the first Official Action in this long series of cases. For these reasons the double patenting rejection over U.S. 5,045,522 is traversed.

Provisional obviousness-type double patenting is also asserted over the claims of application Serial No. 07/679,473 currently pending in Art Unit 1203.

SOUDA et al

Serial No. 08/354,726

In this regard a Terminal Disclaimer is attached as a means of advancing the prosecution. The claims of the pending application will be tailored and suitably adjusted in order to avoid any direct overlap with the claims of the present application once the present application has been allowed.

Reconsideration of this application and favorable action are solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

Leonard C. Mitchard, Reg. No. 29,009
for Arthur R. Crawford
Reg. No. 25,327

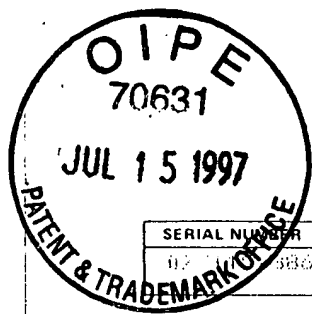
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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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Washington, D.C. 20231

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07 586	11/10/87	SOUDE	5 42377

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DATES DOCKETED

1. 12/21/88
2. 3/21/89
3. 4/21/89

EXAMINER	
FRIED	
ART UNIT	PAPER NUMBER
131	2

DATE MAILED:

MA [REDACTED]

SEP 21 1988

GROUP 120

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of Informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

Claims 1-17 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

s _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1-17 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.

8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable;
☐ not acceptable (see explanation).

10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections **MUST** be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.

12. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

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This application does not contain an Abstract of the Disclosure as required by 37 CFR 1.72(b). An Abstract on a separate sheet is required.

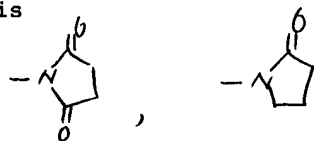
The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Compounds, composition containing the compounds and method of using the compounds wherein

1. ^Z
A. Z is $-\text{O}(\text{CH}_2)_p\text{OR}^4$, $-\text{O}(\text{CH}_2)_q\text{R}^5$,
 $-\text{O}(\text{CH}_2)_r\text{O}(\text{CH}_2)_s\text{OR}^6$, $-\text{S}-\text{A}$, $-\text{N}-\text{CH}_2-\text{C}_6\text{H}_5$, $-\text{O}-\text{R}^9$ wherein
 R^4 , R^5 , A , R^9 contain no hetero group.

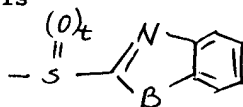
B. Z is



C. Z is



D. Z is



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E. Z is $\begin{array}{c} (O)_t \\ || \\ -S- \end{array}$ pyridyl

F. Z is $\begin{array}{c} -S- \\ || \\ (O)_t \end{array}$ furyl

G. Z is $-O-(CH_2)_q-R^5$ wherein R^5 is heteroaryl. In view of the indefiniteness of heteroaryl. The exact meaning is not certain. However, each heteroaryl is an independent and patentably distinct invention.

II. X is
A $-O-$
B $-S-$
C $\begin{array}{c} -N- \\ | \\ R^3 \end{array}$

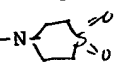
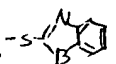

The compounds of the groups derived from various combination of Z and X above are all independent and patentably distinct since they differ greatly in chemical structure. The compounds of group I would not be a reference under 35 USC 103 against the compounds of group II.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of

the other invention.

During a telephone conversation with Mr. Crawford on April 18, 1988 a provisional election was made with traverse to prosecute the invention of group IA IIC, claims 1-5, 12-17 wherein X is N and Z contains no additional hetero group and claims 6-11. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-5, 12-17 wherein X is S or O and Z contains an additional hetero ring are withdrawn from further consideration by the examiner as being drawn to a nonelected invention. See 37 CFR 1.142(b).

Claims 1-5, 12-17 are rejected as being drawn to improper Markush groups. The following reasons apply:

1. Z being ,  can not be considered as conventional substituents, but rather from a new core of a huge complicated molecules each time different Z, X, R¹, R², J. K are present.
2. The only common feature held in common by all of the compounds within the complex molecules of the generic formula is $-S-CH_2-$ . Within the framework of the guidelines set forth in Harnisch, this is an insufficient feature of the compounds considered as a whole to give rise to unity of invention. The claims have been examined only to the extent that they read on the elected invention and should be amended if applicant desires a generic expression of the elected invention.
3. If applicants argue that the generic claim

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represents one invention, then there can be no patentability of the claimed compounds over such art, (pat. 4,255,431, 4,508,905, 4,337,57) and the like. It is noted that there is much greater diversity in structures between the claimed compounds than between some of these compounds and the cited art.

The deletion of the non-elected subject matter would overcome this rejection.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

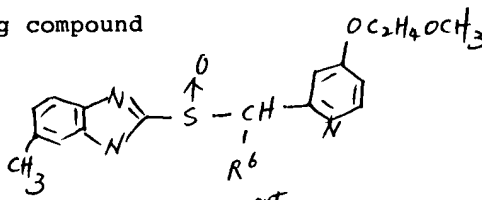
Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-8, 10-17 are rejected under 35 U.S.C. 103 as being unpatentable over Junggren et al. ('431, '257 or '905) or GB 2134523.

Junggren et al. ('431, '257, or '905) and GB 2134523 generically teaches R⁴ being methoxyethoxy or ethoxyethoxy and Junggren specifically teaches (ex. 27)

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the following compound



being ~~homologs~~ as such, the ~~out~~ ^{art} compounds are ^{homologs} of the claimed compounds rendering the claimed compounds unpatentable. The proviso statement only excludes 102b rejection not 103 rejection. For GB 2134523, note page 16, ex. 156, 157.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9, 10 and 12-17 are rejected under 35 U.S.C. 102 (b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over EP 167943, EP 173664, EP 167943 (page 2,4) discloses R₈ being -O(CH₂)_m-O-aryl or -O-(CH₂)_m- aralkyl.

EP 173664 teaches R₇ being (O)_m -(CH₂)_n--R₉ rendering the claims either anticipatory or obvious.

Claims 1-2, 12 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following reasons apply:

1. the term "general" (many occurrences) is

indefinite and ambiguous. This term should be deleted.

2. The terms "aryl", "aralkyl" have no carbon number limitation. Furthermore, aryl reads on multiple rings of twenty or more.

3. The phrase "and a pharmaceutically acceptable salt thereof" should read "or a pharmaceutically acceptable salt thereof".

4. The term "derivative" is indefinite. This term should be deleted.

5. Claim 2 fails to recite an intended use for the composition claim. The term "pharmaceutical composition" is so broad as to include viral, arthritic, hyperlipaemia and the like for which no basis can be found in the disclosure. The claims fail to set out and circumscribe a particular area with any reasonable degree of precision and particularity as required by the second paragraph of 35 USC 112. In re Conley 180 USPQ 454; In re Fredericksen et al 102 USPQ 35; Ex parte Story 169 USPQ 494 and Ex parte Budnick 170 USPQ 230. Although claims should be read in light of the specification, it is not permissible to read limitations from the specification into the claims. In re Priest, 199 USPQ 11.

The specification is objected to for the following reasons:

1. Page 4, pyridine ring is illegible.
2. Page 4, R⁷ should read R².

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3. Page 5, A should be Z

4. Page 7, W definition is lacking.

Applicants' presentation of prior art statement and accompanying references is noted with appreciation. The references have been placed of record in the file.

Any inquiry concerning this communication should be directed to Examiner Jane T. Fan at telephone number 703-557-1456.


JANE T. FAN
PRIMARY EXAMINER
ART UNIT 121

05/04/88;rbb